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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,084	02/12/2002	Eishun Tsuchida	219388US2 CONT	3102
22850	7590	05/28/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			BIANCO, PATRICIA	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/073,084	Applicant(s) TSUCHIDA ET AL. <i>CH</i>	
	Examiner Patricia M Bianco	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>041304</u> . | 6) <input checked="" type="checkbox"/> Other: <u>Final Rejection</u> . |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Response to Arguments

2. Applicant's arguments with respect to claims 1-5 have been considered but are moot in view of the new ground(s) of rejection.

Response to Amendment

3. Applicant's amendment filed 03/05/04 amended claim 1 and added claims 4 & 5.

Allowable Subject Matter

4. The indicated allowability of claim 3 is withdrawn in view of the newly discovered references & rejections based on the newly cited reference(s) follow.

Specification

5. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology, i.e. disclosed and comprises. Correction is required. See MPEP § 608.01(b).

6. The disclosure is objected to because of the following informalities:

It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542.

Although a means for performing a specified function is an acceptable definition of an element, and such a means shall be construed to cover corresponding structure and equivalents thereof, function must be specified and thus would be capable of a determination of structural equivalent thereof; structureless terms without a function specified therefor affords no basis for judging whether a structure different from that

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disclosed by applicant would be equivalent thereof; identity of function is only basis for such equivalency; only where structureless terms specify a function performed by corresponding element of invention does section 112 sanction claiming of that which otherwise would be a self contradiction of purporting to define a structure by use of structureless terms. *Ex parte Klumb*, 159 USPQ 694. In order to be given patentable weight, a functional recitation must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. In *re Fuller*, 1929 C.D. 172; 388 O.G. 279. Appropriate correction is required.

Claim Objections

7. Claims 3 & 5 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

In claim 3, the functional recitation "means for irradiating the vesicle with light" and "means for returning the hemoglobin-vesicle" as not been given patentable weight because it is not fully supported by corresponding structural limitation of similar scope.

35 U.S.C. 112, sixth paragraph, states "[a]n element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof (emphasis added).

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In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC § 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. In re Fuller, 1929 C.D. 172; 388 O.G. 279.

As originally filed, the specification does not provide an explicit definition of what structural elements constitute the claimed means. The specification must explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000)) *Wolfensperger*, 302 F.2d at 955, 133 USPQ at 542.

With respect to claim 3, the term "blood collecting" is used to modify the word "means" in line 3 and the term "isolation" is used to modify the word "means" in line 6, thus purporting to conform to 35 USC 112, sixth paragraph.

With respect to claim 5, the term "oxygen removing" is used to modify the word "means" in line 2, thus purporting to conform to 35 USC 112, sixth paragraph.

However, 35 USC 112, sixth paragraph, requires that the terms specify a function to be performed, thus enabling a determination of the structural equivalent thereof. For example, expressions such as "latch means" or "means for latching" have functional

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connotations and are in conformity with the statute. However, in this case, the term has no functional connotations. See *Ex parte Klumb*, 159 USPQ 694.

Regarding claims 3 & 5, the word "means" is preceded by the word(s) "blood collecting", "isolation", and "oxygen removing" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castle (5,429,594) in view of Sakai et al. "*Physical Properties of Hemoglobin Vesicles as Red Cell Substitutes*" (Biotechnol. Prog. 1996, 12, 119-125). Castle discloses an extracorporeal blood system having blood outlet and inlet lines for withdrawing blood and directing it to a housing (17) where the blood may be subjected to ultraviolet light/irradiation. The blood includes hemoglobin transport vesicles and hemoglobin vesicles naturally occur with a phospholipid layer as an outer layer. The blood will also include naturally amino acids, which may serve as the electron donor. Castle does not teach specifically that the methemoglobin is from a hemoglobin-vesicle containing aqueous hemoglobin solution and an electron donor. With respect to the means plus function and purported means plus function language, they have been treated as a functional recitation since no definitive or explicit structures are disclosed or claimed. Therefore, the tubing and other structural elements of the reference meet these limitations.

Applicant's disclosure teaches a method of providing a hemoglobin-vesicle containing aqueous hemoglobin solution and an electron donor to be used in the claimed method that Sakai et al. for use in red blood cell substitutes.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to providing a hemoglobin-vesicle containing aqueous hemoglobin solution and an electron donor to be irradiated as taught by Castle, since it has been held to be within the general skill of a worker in the art to select a known material on the

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basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

9. Claims 4 & 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castle (5,429,594) & Sakai et al. as applied to claims 1-3 above, and further in view of Bitensky (5,476,764). Castle teaches that the apparatus may include a treatment apparatus (col. 6, lines 21-40), but does not explicitly teach that the apparatus is one that removes oxygen. With respect to the means plus function and purported means plus function language, they have been treated as a functional recitation since no definitive or explicit structures are disclosed or claimed. Therefore, the tubing and other structural elements of the reference meet these limitations.

Bitensky teaches a method for extending the life of red blood cells by removing oxygen from the cells. At the time of the invention, it would have been an obvious matter of design choice to include removing oxygen from the vesicle since the vesicle is an equivalent red blood cell source.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

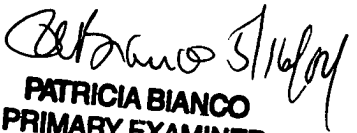
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

May 16th, 2004

Patricia M Bianco
Primary Examiner
Art Unit 3762


PATRICIA BIANCO
PRIMARY EXAMINER